UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,012	02/01/2006	Neil Lee Spector	PR60419USw	9491

23347 7590 12/14/2007

GLAXOSMITHKLINE
CORPORATE INTELLECTUAL PROPERTY, MAI B475
FIVE MOORE DR., PO BOX 13398
RESEARCH TRIANGLE PARK, NC 27709-3398

EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1643	

NOTIFICATION DATE	DELIVERY MODE
12/14/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USCIPRTP@GSK.COM
ROSALIE.M.CHAMBERLAIN@GSK.COM
JULIE.D.MCFALLS@GSK.COM

Office Action Summary	Application No.	Applicant(s)	
	10/567,012	SPECTOR ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3, 6, 7 and 9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6,7 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/01/2006; 02/21/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I (claims 1-3, 6, 7 and 9) in the reply filed on September 19, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 1-3, 6, 7 and 9 are pending.

Claims 4, 5, 8 and 10-28 have been cancelled.

Claim 1 has been amended.

Claims 1-3, 6, 7 and 9 are examined on the merits.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-3, 6, 7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Application Publication number Baselga et al. (Journal of Clinical Oncology 14(3): 737-744, March 1996). Baselga discloses means for determining and measuring HER-2/neu ECD levels in an individual's serum sample having metastatic breast carcinomas that overexpress HER2, see Purpose section of abstract. "Circulating concentration of ECD^{HER2} shed by patients' tumors were...determined using an ELISA.", see page 738, Pharmacokinetics section. This concentration was determined after treatment with rhuMab. This disclosure reads on Applicants' active step listed in claim 1 and hence reads on a method of screening a human subject in need of treatment for a solid epithelial tumor that overexpresses ErbB2, as an aid in selecting between therapy, with Trastuzumab alone and Trastuzumab combined with GW572016, where expression of p95 indicates said subject is more likely to exhibit a favorable clinical response to treatment that includes GW572016 than to treatment that does not include GW572016.

5. Claims 1-3, 6 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication number US 2003/0219842 A1 (filed February 27, 2003). The publication discloses means for determining and measuring HER-2/neu ECD levels in an individual's serum sample having solid tumor cancers of the breast (mammary), ovary, colon, head and neck, bladder, liver and lung before, during and after anti-neoplastic treatment or therapy regimen using immunoassays, see page 3, section 0021; page 4, sections 0039 and 0041; page 5, sections 0050 and 0053; and

page 12, section 0102. This disclosure reads on Applicants' active step listed in claim 1 and hence reads on a method of screening a human subject in need of treatment for a solid epithelial tumor that overexpresses ErbB2, as an aid in selecting between therapy, with Trastuzumab alone and Trastuzumab combined with GW572016, where expression of p95 indicates said subject is more likely to exhibit a favorable clinical response to treatment that includes GW572016 than to treatment that does not include GW572016.

6. Claims 1-3, 6 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Harris et al. (Journal of Clinical Oncology 19(6): 1698-1706, March 15, 2001/ IDS reference 14, submitted February 1, 2006). Harris discloses assessment of *HER-2* ECD in serum samples from breast cancer patients using an enzyme-linked immunoassay, see page 1699, 2nd column, Materials...section. This disclosure reads on Applicants' active step listed in claim 1 and hence reads on a method of screening a human subject in need of treatment for a solid epithelial tumor that overexpresses ErbB2, as an aid in selecting between therapy, with Trastuzumab alone and Trastuzumab combined with GW572016, where expression of p95 indicates said subject is more likely to exhibit a favorable clinical response to treatment that includes GW572016 than to treatment that does not include GW572016.

7. Claims 1, 2, 6 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Molina et al. (Clinical Cancer Research 8: 347-353, February 2002/ IDS reference 3, submitted February 21, 2007). Molina discloses a method of p95 analysis in breast cancer tissues implementing western blot analysis, see page 348, 2nd column, Western...section; Table 1 on page 349. This disclosure reads on Applicants' active step listed in claim 1 and hence reads on a method of screening a human subject in need of treatment for a solid epithelial tumor that overexpresses ErbB2, as an aid in selecting between therapy, with Trastuzumab alone and Trastuzumab combined with GW572016, where expression of p95 indicates said subject is more likely to exhibit a favorable clinical response to treatment that includes GW572016 than to treatment that does not include GW572016.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-3, 6, 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication number US 2003/0219842 A1 (filed February 27, 2003), and further in view of Baselga et al. (Journal of Clinical Oncology 14(3): 737-744, March 1996). The publication teaches methods for

determining and measuring HER-2/neu ECD levels in an individual's serum sample having solid tumor cancers of the breast (mammary), ovary, colon, head and neck, bladder, liver and lung before, during and after anti-neoplastic treatment or therapy regimen using immunoassays, see page 3, section 0021; page 4, sections 0039 and 0041; page 5, sections 0050 and 0053; and page 12, section 0102. The anti-neoplastic treatment or therapy may be an anti-HER2/neu antibody-based immunotherapy. The publication does not teach the claimed method wherein a subject has been previously treated with trastuzumab before determining whether the tumor expresses p95.

However, Baselga teaches the administration of rhu-MAb HER2 also known as Herceptin® (trastuzumab) was administered to patients with metastatic breast carcinomas that overexpressed HER2 and circulating ECD^{HER2} was assessed before and after rhU-Mab HER2 treatment, see Patients...section of the Abstract; Table 2 on page 739; and Figure 1 on page 740. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to assess the level of the ECD in a subject's serum after the treatment with trastuzumab as taught in the publication and Baselga. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings in both references to determine the level of ECD in the sera of patients before and after cancer treatment in order to determine the course of disease and monitor disease progression or regression because it is art known ECD serves as an indicator of treatment effectiveness, see abstract of publication; paragraph bridging pages 4 and 5; and page 12, section 0102; and Baselga, page 739, 2nd column, 1st full paragraph.

10. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER

Alana M. Harris, Ph.D.
10 December 2007